

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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	:	
CYRILLE TINKER,	:	
	:	
Plaintiff,	:	CASE NO. 07 CV 5838 (MGC)
	:	
-against-	:	
	:	DEFENDANTS JOHNSON & JOHNSON,
JOHNSON & JOHNSON, JOHNSON &	:	JOHNSON & JOHNSON
JOHNSON PHARMACEUTICAL	:	PHARMACEUTICAL RESEARCH &
RESEARCH & DEVELOPMENT, L.L.C.,	:	DEVELOPMENT, L.L.C., ALZA
ALZA CORPORATION, ORTHO-McNEIL	:	CORPORATION AND ORTHO-McNEIL
PHARMACEUTICAL, INC., and DOES 1	:	PHARMACEUTICAL, INC.'S ANSWER,
through 100,	:	AFFIRMATIVE DEFENSES AND JURY
	:	DEMAND
	:	
Defendants.	:	
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Defendants Johnson & Johnson ("J&J"), Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("J&JPRD"), Alza Corporation ("Alza") and Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), (collectively referred to herein as "Defendants"), by and through their undersigned counsel, hereby respond to the Complaint (the "Complaint") filed by Plaintiff Cyrille Tinker (referred to herein as "Plaintiff") as follows:

1. Responding to Paragraph 1 of the Complaint, Defendants state that they have no knowledge as to where Plaintiff resides and therefore are without sufficient knowledge or information to form a belief as to the truth of the allegations contained therein.

I. NATURE OF THE ACTION

2. In response to Paragraph 2 of the Complaint, Defendants deny that Ortho Evra®

caused any injury to Plaintiff. Responding further, Defendants are without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 2 of the Complaint.

3. Defendants deny the allegations contained in Paragraph 3 of the Complaint.

II. DEFENDANTS

4. Defendants admit the allegations contained in Paragraph 4 of the Complaint.
5. Defendants admit the allegations contained in Paragraph 5 of the Complaint.
6. Defendants admit the allegations contained in Paragraph 6 of the Complaint.
7. Defendants admit the allegations contained in Paragraph 7 of the Complaint.
8. The allegations in Paragraph 8 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 of the Complaint.

9. Defendants deny the allegations contained in Paragraph 9 of the Complaint.

III. JURISDICTION

10. The allegations contained in Paragraph 10 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants admit only that Plaintiff has alleged jurisdiction over this action. Responding further, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Furthermore, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as Ortho Evra®. Defendants otherwise deny the remaining allegations contained in Paragraph

10 of the Complaint.

11. In response to the allegations contained in Paragraph 11, Defendants admit that Alza manufactured Ortho Evra® patches sold in the United States. Defendants otherwise deny the allegations contained in Paragraph 11 of the Complaint.

IV. FACTUAL ALLEGATIONS

12. In response to the allegations contained in Paragraph 12, Defendants admit that Alza manufactured Ortho Evra® patches sold in the United States. Responding further, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as Ortho Evra®. Furthermore, Defendants admit that the contraceptive product known as Ortho Evra® received approval from the Food and Drug Administration as a prescription drug on or about November 20, 2001. Defendants otherwise deny the allegations contained in Paragraph 12 of the Complaint.

13. Defendants admit the allegations contained in Paragraph 13 of the Complaint.

14. Defendants deny the allegations contained in Paragraph 14 of the Complaint.

15. Defendants deny the allegations contained in Paragraph 15 of the Complaint.

16. To the extent that Paragraph 16 of the Complaint refers to a document, Defendants state that the document speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 16 of the Complaint.

17. To the extent that Paragraph 17 of the Complaint refers to a document, Defendants state that the document speaks for itself and refer to that document for a fair and

accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 17 of the Complaint.

18. Defendants deny the allegations contained in Paragraph 18 of the Complaint.

19. To the extent that Paragraph 19 of the Complaint refers to a document, Defendants state that the document speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 19 of the Complaint.

20. In response to Paragraph 20 of the Complaint, Defendants admit that Ortho-McNeil utilized direct-to-consumer advertising to market, promote, and/or advertise the contraceptive product known as Ortho Evra®. Defendants otherwise deny the allegations contained in Paragraph 20 of the Complaint.

21. In response to Paragraph 21, Defendants admit that Ortho-McNeil marketed, promoted and/or advertised the contraceptive product known as Ortho Evra® to health care providers. Defendants otherwise deny the allegations contained in Paragraph 21 of the Complaint.

22. To the extent that Paragraph 22 refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 22 of the Complaint.

23. To the extent that Paragraph 23 refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in

Paragraph 23 of the Complaint.

24. To the extent that Paragraph 24 refers to a package insert or other document, Defendants state that the package insert or document speaks for itself and refer to that package insert or document for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 24 of the Complaint.

25. To the extent that Paragraph 25 refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 25 of the Complaint.

26. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 26 of the Complaint.

27. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 27 of the Complaint.

28. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 28 of the Complaint.

29. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 29 of the Complaint.

30. To the extent that Paragraph 30 refers to Plaintiff's state of mind, Defendants are

without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 30 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 30 of the Complaint.

31. To the extent that Paragraph 31 refers to the state of mind of Plaintiff or others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 31 of the Complaint.

32. To the extent that Paragraph 32 refers to a package insert or other document, Defendants state that the package insert or document speaks for itself and refer to that package insert or document for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 32 of the Complaint.

33. Responding to Paragraph 33 of the Complaint, Defendants admit that on or about November 10, 2005, FDA approved updated labeling for the contraceptive product known as Ortho Evra®. To the extent that Paragraph 33 refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 33 of the Complaint.

34. To the extent that Paragraph 34 of the Complaint refers to a document, Defendants state that the document speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 34 of the Complaint.

35. Defendants deny the allegations contained in Paragraph 35 of the Complaint.

36. To the extent that Paragraph 36 refers to the state of mind of Plaintiff or others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 36 of the Complaint.

37. In response to Paragraph 37 of the Complaint, Defendants deny that Ortho Evra® caused any injury to Plaintiff. Responding further, Defendants are without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 37 of the Complaint.

V. FIRST CAUSE OF ACTION:
STRICT LIABILITY / DEFECTIVE MARKETING & FAILURE TO WARN

38. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

39. To the extent that Paragraph 39 refers to a package insert or document, Defendants state that the package insert or document speaks for itself and refer to that package insert or document for a fair and accurate portrayal of its contents. Responding further, Defendants deny that the contraceptive product known as Ortho Evra® is “defective,” and therefore deny the allegations contained in Paragraph 39 of the Complaint.

40. Defendants deny the allegations contained in Paragraph 40 of the Complaint.

41. Defendants deny the allegations contained in Paragraph 41 of the Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of the Complaint.

43. To the extent that Paragraph 43 refers to a package insert or document, Defendants state that the package insert or document speaks for itself and refer to that package insert or document for a fair and accurate portrayal of its contents. Defendants otherwise deny

the allegations contained in Paragraph 43 of the Complaint

44. To the extent that Paragraph 44 refers to the state of mind of Plaintiff or others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 44 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 44 of the Complaint.

VI. SECOND CAUSE OF ACTION:
NEGLIGENCE

45. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

46. Defendants deny the allegations contained in Paragraph 46 of the Complaint.

47. Defendants deny the allegations contained in Paragraph 47 of the Complaint.

48. Defendants deny the allegations contained in Paragraph 48 of the Complaint.

49. Defendants deny the allegations contained in Paragraph 49 of the Complaint.

VII. THIRD CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

50. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

51. To the extent that Paragraph 51 refers to Plaintiff's state of mind, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 51 of the Complaint

52. Defendants deny the allegations contained in Paragraph 52 of the Complaint.

53. To the extent that Paragraph 53 refers to the state of mind of Plaintiff or others,

Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 53 of the Complaint

54. Defendants deny the allegations contained in Paragraph 54 of the Complaint.

55. Defendants deny the allegations contained in Paragraph 55 of the Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of the Complaint.

PRAYER FOR RELIEF

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.